CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 22.1
TITLE: PHARMACY

AUTHORITY: 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.4(b)(2)(v), b(3)(iii), (b)(5)(v), (d)(3)(vi), and (e)(11)(i)

I. EFFECTIVE DATE

A. Labeled use: the effective date of U.S. Food and Drug Administration (FDA) approval for the specific labeled indication/use.

B. Off-labeled use: the effective date of the FDA approval for the latest specific labeled indication/use; or if medical literature supports prior safety and efficacy, the first effective date of FDA approval of the drug for general use in humans may be used.

C. Orphan drugs: the effective date of the FDA's marketing approval (MA) for the proposed use. Orphaned drugs are defined as a drug or biological product that is used for the diagnosis, treatment, or prevention of a rare disease or condition. A rare disease is defined as affecting fewer than 1 in 200,000 persons in the United States.

II. POLICY

A. Drugs and medicines, including "unlabeled or off-label indications," administered by a physician or obtained by prescription, are covered when:

1. Labeled Indications:

a. The drug or medicine is approved by the U.S. Food and Drug Administration (FDA).

b. The drug or medicine is prescribed or ordered by a physician or other authorized professional provider who has determined the drug as medically necessary for the treatment of the condition.

c. The drug or medicine is prescribed and dispensed in accordance with all applicable state laws and licensing requirements.

2. Off-label Use. Approval for “unlabeled or off-label use” requires medical review for medical necessity. Drugs or medicines may be cost shared for off-label use when there is reliable evidence, such as clinical studies, demonstrating such usage is safe and effective and generally accepted standard of practice in the general medical community. The following hierarchy of reliable evidence is used:

a. well controlled clinical studies, published in referenced medical literature,

b. published in formal technology assessments (i.e., The Hayes Assessment),

c. published in national medical policy organizations (i.e., American Heart Association, American Medical Association, etc.), and

d. published in reports of national expert opinion organizations (i.e., The American Cancer Society).

3. If the "off-label or unlabeled" use of the drug is questionable regarding the safety, effectiveness, or whether it is a nationally accepted standard in the medical community, VA cost sharing of the drug will be denied.

4. Drugs grand fathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered as if FDA approved. (A drug that is approved for testing in humans is not covered.) Information concerning FDA approved drugs may be obtained by calling 1-888-INFOFDA or by visiting the FDA web site at www.fda.gov/cder/da/ddpa.htm.

5. Drugs which previously required a prescription but which are now deemed safe by the FDA for use without a doctor's prescription, and are available over-the-counter, are not reimbursable. Examples are: Dimetapp, Sominex, Bactine, Cortaid, Coricidin Nasal Mist, Ocuclear, E-Z Scrub 241, Trosyd, Actifed, and Clotrimazole (trade name Gyne-Lotrimin).

B. The prescription and the number of authorized refills will not result in more than a 12-month supply.

1. No more than a 90-day supply of medication will be filled at one time.

2. Controlled substances (Schedule III, IV, and V) will be covered for a 30-day supply with a maximum of 5 refills in a 6-month period. The exception to this is for controlled substances used for seizure control. These prescriptions may be dispensed in up to 90-day quantities with one refill.

3. Schedule II controlled substances prescriptions will be covered for a 30-day non-refillable supply and will require a new prescription for each 30-day period. The exception to this is for drugs used for treating Attention Deficit Disorder, which can be dispensed in up to 90-day quantities.

4. No prescription may be refilled until 75 percent of the prior prescription is expended unless the patient or doctor provides a suitable explanation as to why the early fill is necessary.

III. POLICY CONSIDERATIONS

A. Insulin and related supplies may be cost shared for diabetic patients regardless of whether or not a prescription is required under state law. Insulin pumps may be cost shared for beneficiaries only when the diagnosis is insulin dependent Type I diabetes mellitus (see Chapter 2, Section 17.5, *External Infusion Pump)*.

B. Beneficiaries who reside in the United States and order their prescriptions from foreign countries must comply with the same criteria as outlined within this policy. Reimbursement will be made in accordance with the cost sharing procedures outlined within Chapter 3, Section 5.11, *Pharmacy Reimbursement.*

C. CHAMPVA shall accept store/pharmacy sales receipts (i.e., cash register receipt) with a date and dollar amount that corresponds to the date and dollar amount on the pharmacy's invoice/billing statement.

1. Minimum data requirements:

a. the name of the patient,

b. the name of pharmacy, address, and phone number,

c. the name of prescribing physician,

d. National Drug Code (NDC), the name, strength, and quantity of each drug,

e. an itemized charge for each drug, and

f. the date the prescription was filled.

Note: Because prescriptions are paid as billed, "Your Pharmacy" will be used on the explanation of benefits (EOB) for non-assigned prescription claims. The name and address of a pharmacy is not required for claim history and EOB

purposes, however, this does not relax the requirement for provider identification information on the pharmacy receipt or drug listing. Prescriptions for controlled substances written by providers who do not have individually assigned DEA numbers shall not be accepted. Claims for medical supplies or DME purchases from pharmacies are not included in this category. If the beneficiary has a "prepaid prescription plan" where the beneficiary pays only a "flat fee" no matter what the actual cost of the drug, CHAMPVA shall cost share the fee and not develop for the actual cost of the drug, since the beneficiary is only liable for the "fee."

2. Drug Claim Tolerances.

Normally, all of the above information is required. However, outpatient institutional claims containing only drugs (whether controlled or uncontrolled drugs) need not be developed for diagnosis, correct beneficiary signature, strength of drug, quantity, or prescription number when the total billed charge on the claim is $250.00 or less.

D. Treatment of organic male impotence will be covered only after thorough evaluation has been documented by the physician.

a. Viagra (Sildenafil), prescribed by physicians treating male patients diagnosed with organic impotence, may be cost shared when the physician has considered the medication as the most optimal regime for the patient.

b. Only 6 tablets of Viagra per month (in accordance with established clinical guidelines) may be dispensed. “Lost”, “stolen”, or “destroyed” tablets will not be replaced.

IV. EXCLUSIONS

A. Drugs and medicines that are not approved for marketing by the FDA.

B. Investigational drugs with FDA "Group C" designations has reproducible efficacy in one or more specific tumor types. Such a drug has altered or is likely to alter the pattern of treatment of the disease and can be safely administered by properly trained physicians without specialized supportive care facilities. CHAMPVA cannot cost share use of Group C designated drugs because authorization for Group C distribution for a specific indication is not equivalent to formal FDA approval for that indication. Medical care related to the use of Group C designated drugs may be cost shared only when the care would have been provided with nationally accepted standard of practice in the medical community.

C. Drugs and medicines prescribed or provided by a member of the beneficiary's immediate family, or a person living in the beneficiary or sponsor's household. [38 CFR 17.272(a)(15)]

D. Drugs and medicines prescribed in connection with cosmetic surgery that is performed to primarily improve physical appearance or for psychological purposes to restore form without correcting or materially improving a bodily function. [38 CFR 17.272(a)(19)]

E. Drugs and medicines prescribed for nonsurgical treatment of obesity, dietary control, or weight reduction (with exception of gastric bypass, gastric stapling, or gastroplasty procedures in connection with morbid obesity when determined to be medically necessary). [38 CFR 17.272(a)(22)]

F. Nonprescription contraceptives. [38 CFR 17.272(a)(29)]

G. Vitamins or other nutritional supplements, including those related to prenatal care for a home patient whose condition permits oral feeding, except when documentation indicates the use of the vitamin is an accepted standard of practice for the specific treatment of a covered medical condition. [38 CFR 17.272(a)(51)]

H. Smoking cessation drugs and supplies (i.e., nicotine patches). [38 CFR 17.272(a)(57)]

I. Prescriptions to be utilized in drug maintenance programs where one addictive drug is substituted for another, such as methadone substituted for heroin. [38 CFR 17.272(a)(72)]

J. All medications not requiring a prescription (over-the-counter purchases) except for insulin and related diabetic testing supplies and syringes. [38 CFR 17.272(a)(80)]

K. Prescriptions written after the beneficiary's eligibility period has expired.

L. The following list of drugs may not be cost shared for “unlabeled or off-label use. The list is not all-inclusive.

1. Adrenal cortex extract injections.

2. Autotogenous vaccines.

3. Gemcitabine (Gemzar®) for the treatment of non-small cell lung cancer.

4. Heparin therapy in the treatment of pregnant patients who have systemic lupus erythematosus (SLE) or who have lupus anticoagulant (LA).

5. High dose calcitriol and/or interferon gamma in the treatment of malignant osteopetrosis.

6. Human chorionic gonadotropin (HCG) or any other drug administered for purposes of weight control.

7. Interferon.

   a. fa-2b for treatment of bladder cancer.

   b. interferon gamma for the treatment of scleroderma.

8. Intravenous injections of gamma globulin for pregnancy rejection and polycystic ovarian disease.

9. Intravenous immune globulin (IVIG) (Venoglobulin®) in the treatment of multiple sclerosis.

10. Isotretinoin (Accutane®) as a single-agent treatment or for maintenance of remission of squamous cells carcinoma of the skin.

11. Laetrile (amygdalin, sarcarcinase, vitamin B-17) and all other drugs characterized as a "nitriloside" are not recognized to be safe and effective for any therapeutic use.

12. Methotrexate for systemic lupus erythematosus.

13. Mitomycin-C (Mutamycin®) when used in trabeculectomy (glaucoma filtering surgery).

14. Myocophenolate Mofetil (Cellcept®) for the prophylaxis of organ rejection in patients receiving heart transplantation or liver transplantation.

15. Navelbine® for refractory platinum-resistant epithelial ovarian cancer.

16. Paclitaxel (Taxol®) for the treatment of malignant melanoma.

17. Pamidronate (Aredia®) for the treatment of osteoporosis.

18. Placebo injections and drugs. [38 CFR 17.272(a)(14)]

19. Transdermal nicotine patch for the treatment of ulcerative colitis.

20. Treatment Investigational New Drugs (INDs) not approved by the FDA for commercial marketing or general uses.

Note: Medical care related to the use of treatment INDs may be cost shared when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

END OF POLICY